# Exhibit A

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

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|---|---|
| Biomedical Device Consultants & Laboratories of Colorado, LLC,<br><br>Plaintiff,<br><br>vs.<br><br>TA Instruments - Waters LLC,<br><br>Defendant. | Civil File No. 17-cv-03403 DWF/SER<br><br>**PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR PRELIMINARY INJUNCTION** |

## INTRODUCTION

Plaintiff Biomedical Device Consultants & Laboratories of Colorado, LLC ("BDC") sells equipment for testing medical devices. Its best-selling system, the VDT-3600i, is used for testing the durability of prosthetic heart valves. The VDT-3600i (and its use) is covered by a family of patents, including U.S. Patent Nos. 8,584,538 ("the '538 Patent"), 8,627,708 ("the '708 Patent"), 9,186,224 ("the '224 Patent"), 9,237,935 ("the '935 Patent") (collectively, the "Patents-in-Suit"). The technology behind the VDT-3600i made it the market standard, rendering prior products obsolete and earning BDC the dominant market position and a reputation for innovation. Attempting to capitalize on this new technology pioneered by BDC, Defendant TA Instruments – Waters, LLC ("TA Instruments") is now offering an infringing test system known as the DuraPulse Heart Valve Test Instrument ("DuraPulse"). TA Instruments' infringement must be stopped by a preliminary injunction.

All four *Dataphase* factors favor a preliminary injunction. BDC is likely to prevail at trial in showing that the TA Instruments' product infringes. Its DuraPulse product meets each and every limitation of the asserted claims of the patents. For example, the DuraPulse employs an "excess volume area" that helps dissipate pressure spikes, capitalizing on one unique feature of the patents. Without an injunction, BDC will suffer irreparable harm. Specifically, it will lose the market share that it has built. Although relatively small, the market at issue has strong incumbency effects—customers purchase test systems from only one supplier in order to minimize testing variables. Moreover, lost market share will reduce revenue for BDC available for research and development—vitally important in an industry where test systems suppliers must keep up with highly innovative medical device makers. BDC will also suffer injury to its reputation for innovation from having to compete with a copyist. Finally, TA Instruments is also undercutting BDC's price, threatening to cause price erosion.

The other preliminary injunction factors—balance of the harms and public interest—also favor injunctive relief. For these reasons, and the others discussed below, BDC's motion for preliminary injunction should be granted.

## BACKGROUND

### A. Field of Technology

This case concerns equipment used for testing the durability of prosthetic heart valves. Before any medical device is marketed it must meet certain regulatory standards. Girard Decl. ¶ 6. Prosthetic heart valves must be tested to ensure that they will function for the anticipated life of a patient by opening and closing under the flows and pressures

that are present within the human vascular system. *Id.* ¶ 7. International bodies, such as the International Organization for Standardization ("ISO"), set the standards for testing the durability of heart valves. *Id.* ¶ 6. Testing standards require that prosthetic valves be able to withstand a certain number of cycles of opening and closing of the valve leaflets, usually in the hundreds of millions (representing years of service in a human body), and that a specific pressure differential be generated across the valve when closed. *Id.* ¶ 7. In order to complete hundreds of millions of cycles in a commercially viable timeframe, durability testing is done on an "accelerated" basis. *Id.* ¶ 8. In other words, the speed of the cycles is faster than a normal human heartbeat (a normal beat rate is 70 beats per minute ("bpm")). *Id.* Using current technology at accelerated cycling of 800 bpm, testing takes approximately six months. *Id.*

Providing fluid flow through the test valve and pressure across it requires a "drive mechanism" such as a pump that drives fluid into a test chamber. *Id.* Before commercialization of the technology of the Patents-In-Suit, durability testing equipment (and methods of using that equipment) used drive mechanisms that had limited control over the closing rate and often produced "pressure spikes" when maintaining pressure above the testing threshold for the amount of time required by testing standards. *Id.* ¶ 10. These pressure spikes are undesirable because they wear out valves during testing faster than they would be worn out in the human body, causing false test failures. *Id.* In addition, prior designs of testing equipment experienced operational problems. For example, one prior art device used a flexible metallic bellows to pressurize. '538 Patent col.1 ll.34-36. However, in such a system, a higher load is required to drive the metallic

bellows and can thus impact the reliability of the test system and increase maintenance requirements which increases the already lengthy durability testing process. Girard Decl. ¶ 11.

### B. The Patents-in-Suit Are Inventions Representing An Improved Testing System

To better manage the valve closing dynamics and differential pressure spikes, and thus better comply with the durability testing standards, BDC developed a novel test system that placed an "excess volume area" on the outflow side of a sample test valve. Weinberg Decl. ¶ 6. BDC employees also developed a method of operating the test system using this excess volume area that helps control differential pressure spikes. *Id.* An example of such a system from the Patents-in-Suit is shown below:

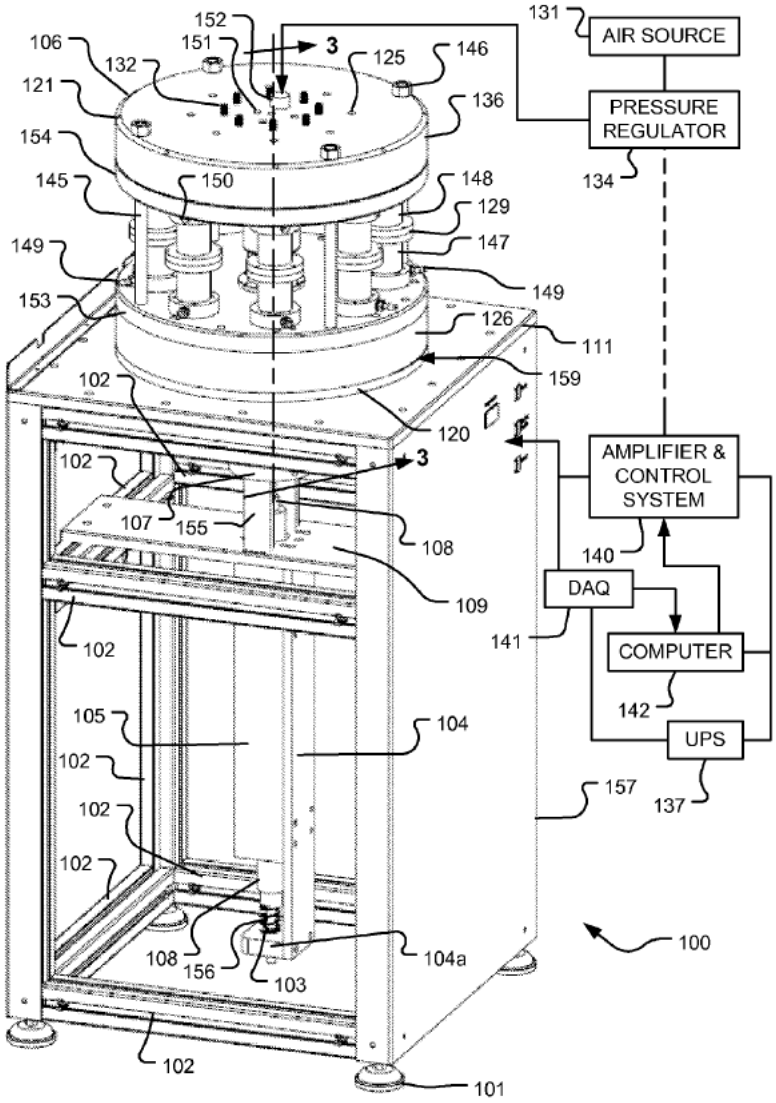
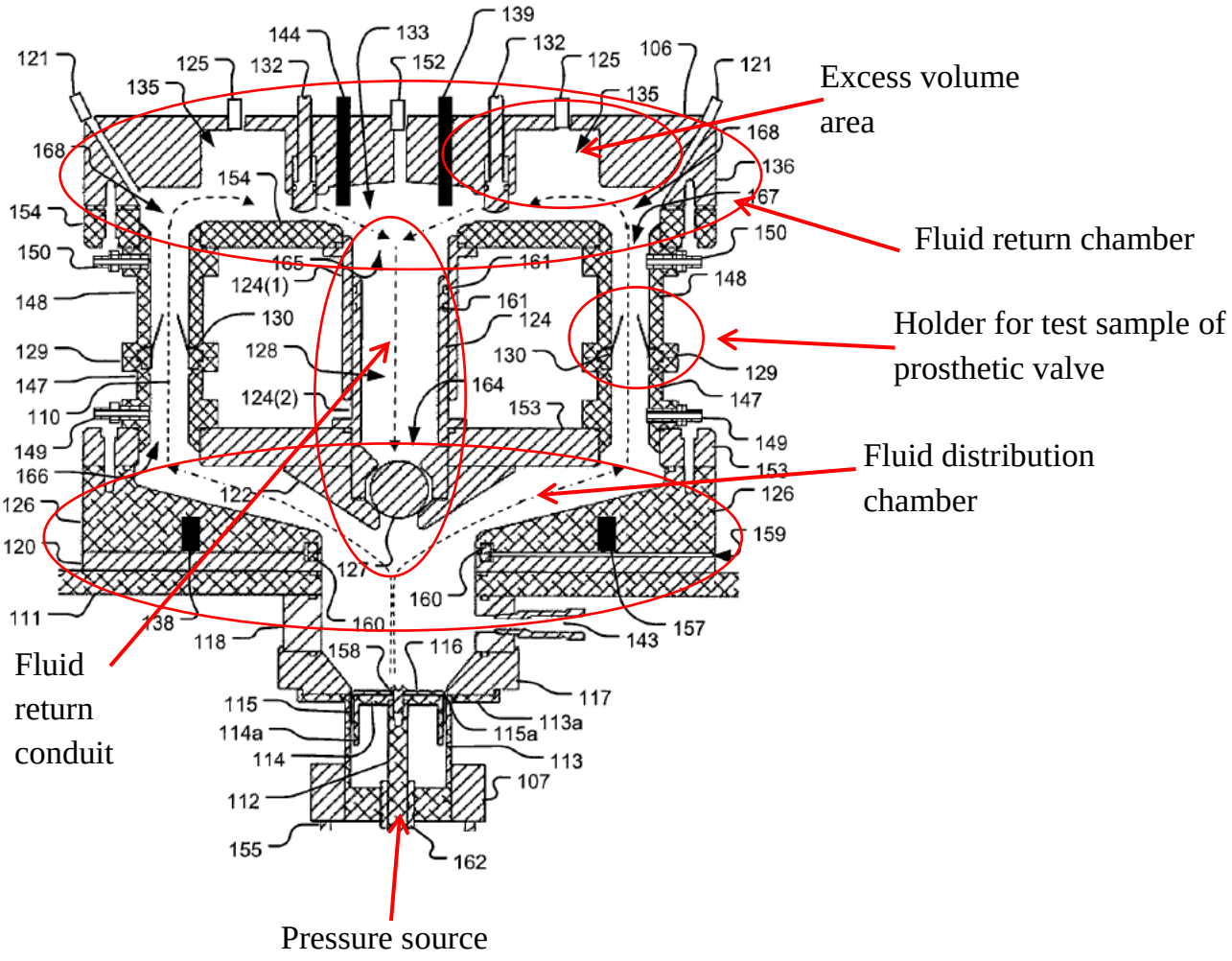



**Fig. 1**

’538 Patent Fig. 1.

The Patents-In-Suit cover different elements of the device or its operation. For example, the ’935 Patent covers a device with several components including a test chamber that has an “excess volume area” that is connected to a return chamber. Similarly, another patent, the ’224 Patent, covers a method for operating a test system with an excess volume area. The excess volume area and return chamber within the test chamber are shown below:




This excess volume area improves the test environment by minimizing unnatural and undesirable pressure spikes and provides advantages of speed and longevity in the drive system. Girard Decl. ¶ 15. Specifically, the excess volume area can alleviate some of the system pressure during the drive phase. *Id.* The excess volume area also reduces pressure recoil by releasing fluid downstream of the valve during the return phase (when pressure is released) that helps build pressure back up on that side of the valve. *Id.*

### C. BDC Competes in the Market For Heart Valve Durability Test Equipment Using the Patents-in-Suit

The Patents-in-Suit revolutionized the market for heart valve durability testing equipment by providing an accelerated testing device with an excess volume area known as a compliance chamber on the outflow side of the valve. Weinberg Decl. ¶ 8. BDC has commercialized the Patents-in-Suit with its VDT-3600i heart valve durability tester. *Id.* The VDT-3600i has become a core component of BDC's overall business; the VDT-3600i is BDC's best-selling medical device test system. *Id.* ¶ 13.

The specialized nature of heart valve durability systems means there are a limited number of competitors in the marketplace. *Id.* ¶ 10. Before TA Instruments' entry into the market (discussed below), BDC had no competitors who offered a system that worked on the same principals as BDC's. In fact, its only competitors were Dynatek Labs and ViVitro Labs, both of whom used entirely different technology that was rendered obsolete by BDC's patented device and method. *Id.* The superior performance of the VDT-3600i led to it becoming the industry standard for heart valve durability testing. *Id.* As a result, BDC's VDT-3600i has an estimated 80-90% worldwide market share. *Id.* ¶ 11.

Market share in the heart valve durability testing equipment market is important due to incumbency effects. *Id.* A single testing system can only test a few devices at a time (both BDC and TA Instruments sell systems that test a maximum of six prosthetics at a time). *Id.* To bring a new prosthetic valve device to market, however, medical device manufacturers need testing data from many (often dozens) of sample devices. *Id.*

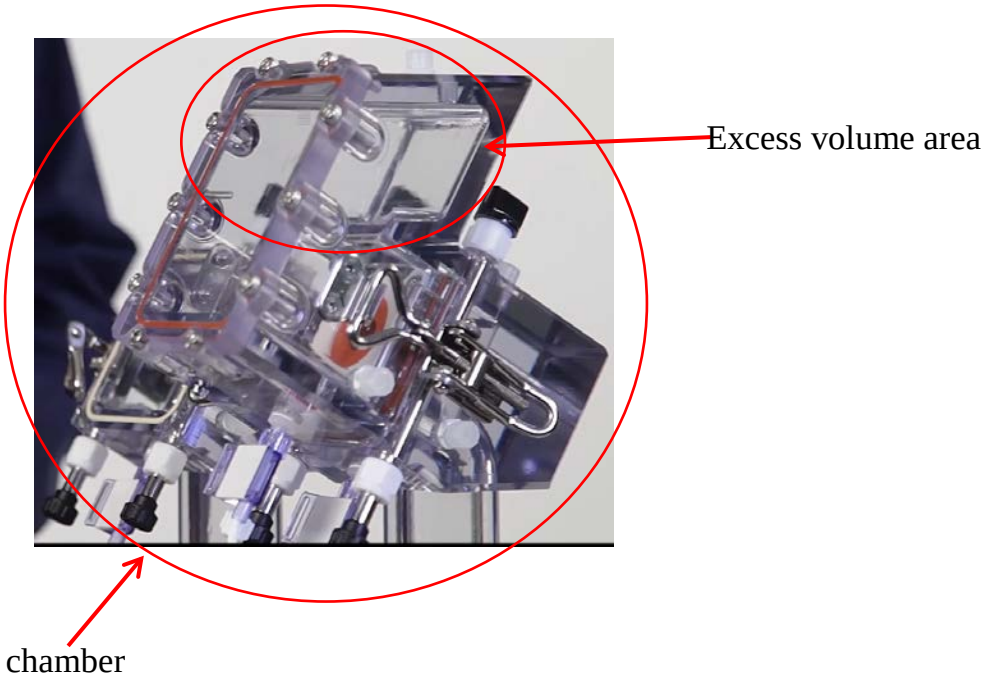
Therefore, testing system customers need multiple systems. *Id.* Customers will generally purchase a single testing system and run a pilot program. *Id.* If the pilot is successful, the customer will then purchase a larger number of the same testing system. *Id.* Customers generally do not buy testing equipment for a single device from multiple sources in order to avoid introducing additional testing variables (i.e., differences between testing machines from different suppliers) into the test data that would be submitted to the FDA or international regulatory agencies. *Id.* ¶ 12. The lifespan of valve durability testing equipment is often ten to fifteen years, meaning that once a customer has decided which testing equipment to use, it will likely be a long time before a competitor has the opportunity to usurp the place of an incumbent. *Id.*

In addition to incumbency effects, innovation and reputation for innovation are extremely important in the market for heart valve durability testing. *Id.* ¶ 14. Prosthetic heart valves have seen significant improvements in recent years resulting in larger sizes and different methods of securing in place within the human body. *Id.* ¶ 4. This has required similar innovations in testing equipment. *Id.* Accordingly, customers often make decisions based on reputation for innovation. *Id.* ¶ 14. A testing system supplier's long-term success is dependent upon that reputation. *Id.*

### D. TA Instruments' DuraPulse Tester Infringes the Patents-in-Suit and Competes Against BDC's VDT-3600i

TA Instruments sells a heart valve testing system known as the DuraPulse Heart Valve Test Instrument ("DuraPulse"). *Id.* ¶ 15. The DuraPulse is a device for accelerated durability testing of prosthetic heart valves. *See DuraPulse Heart Valve Test*

*Instrument* available at http://www.tainstruments.com/heart-valve-durability-test-instrument/. As shown below, the DuraPulse includes all the elements of the testing system claimed by Patents-in-Suit. For example, the DuraPulse has a test chamber with an excess volume area:




Girard Decl. ¶ 22.

TA Instruments' DuraPulse test system competes directly with BDC's. Weinberg Decl. ¶ 22. According to TA Instruments' counsel, TA Instruments has sold very few (less than half a dozen) products to date. However, BDC has lost its place in the market as the only testing system of its kind and its reputation for innovation will be harmed if the VDT-3600i's status as a unique product is not reinstated. *Id.* ¶ 23. Furthermore, TA Instruments has undercut BDC's price in head-to-head competitive bidding for customers. *Id.* ¶ 22. Even though TA Instruments' "list price" for the DuraPulse is higher than BDC's price for the VDT-3600i, TA Instruments has offered discounts to

customers to attract business. *Id.* As a result, BDC has lost at least one sale to TA Instruments. *Id.* Given that TA Instruments has sold less than a half dozen products to date, the fact that one of those sales was at the expense of a BDC sale is obviously significant.

**E. BDC Attempts to Stop the Irreparable Harm Through Negotiation, But is Unsuccessful.**

In October 2013, BDC observed a prototype of the DuraPulse system, which at the time was being developed by Bose Corporation ("BOSE"). Weinberg Decl. ¶ 16. In July 2014, BDC learned that BOSE was offering the DuraPulse for sale and sent a letter to BOSE notifying it of potential infringement by the DuraPulse of the '538 and '708 Patents, the only Patents-in-Suit that had issued at that time. *Id.* BDC also alerted BOSE of its application for the '935 Patent. *Id.* BOSE denied infringement of the '538 and '708 Patents and refused to address the application for the '935 Patent, as it had not yet issued. *Id.*

At the time, it appeared that BOSE's sales and marketing of the DuraPulse were negligible and its potential infringement, while concerning to BDC, did not pose an imminent threat to BDC's market position or reputation. *Id.* ¶ 17. However, BOSE then sold its ElectroForce division and product line, which included the DuraPulse, to TA Instruments in 2015. *Id.* ¶ 18. After acquiring ElectroForce, TA Instruments dramatically increased its marketing efforts for the DuraPulse. *Id.* After studying TA Instruments' now-available promotional materials for DuraPulse, infringement of the

Patents-in-Suit, especially recently issued patents,[1] became very clear. *Id.* ¶ 19. Accordingly, on February 23, 2016, BDC notified TA Instruments of its infringement of the Patents-in-Suit. *Id.* ¶ 20. The parties thereafter exchanged a series of communications and studies concerning TA Instruments' defenses to BDC's claims. *Id.*

In early 2017, while the parties were involved in these exchanges, TA Instruments sold at least one of the infringing DuraPulse products to a customer BDC was contemporaneously offering to sell the VDT-3600i by undercutting BDC's price. *Id.* ¶ 22. Thus, it became clear that TA Instruments was simply trying to draw out the discussions while improving its position in the market. *Id.* Because of that sale, the DuraPulse has become a real threat to the market position, price, and reputation of the VDT-3600i. The only means for BDC to prevent irreparable harm was to commence an action, which it did on July 27, 2017. After service of the complaint in this action, TA Instruments requested an opportunity to negotiate a settlement. After a number of weeks of discussion, it became clear that the terms proffered by TA Instruments were inadequate.[2] Accordingly, BDC now brings this motion for preliminary injunction.

## ARGUMENT

### A. Standard of Review

Federal Circuit law governs the substantive aspects of a decision to grant a preliminary injunction in a patent case. *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446,

[1] The '224 Patent issued November 17, 2015 and the '935 Patent issued January 19, 2016. '224 Patent at [45]; '935 Patent at [45].
[2] TA Instruments also brought a motion to dismiss this action, the briefing for which was recently completed.

1451 n.12 (Fed. Cir. 1988). Regional Circuit law governs "purely" procedural questions involving the grant of a preliminary injunction. *Id.* A plaintiff seeking a preliminary injunction must establish (1) that the plaintiff is likely to succeed on the merits; (2) that the plaintiff is likely to suffer irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in the plaintiff's favor, and (4) that an injunction is in the public interest. *Dataphase Sys., Inc. v. C.L. Sys., Inc.*, 640 F.2d 109, 1114 (8th Cir. 1981). Under Eighth Circuit law, no single factor is dispositive, but the probability of success factor is the most significant. *Home Instead, Inc. v. Florance*, 140 F.3d 721 F.3d 494, 497 (8th Cir. 2013). Injunctive relief is an important remedy against patent infringement. *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1362 (Fed. Cir. 2012) ("the axiomatic remedy for trespass on property rights is removal of the trespasser").

**B. BDC Is Likely To Prevail on the Merits**

To establish that it is likely to succeed on the merits, BDC must establish that at least one claim of the Patents-in-Suit is valid and infringed. *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). An "issued patent comes with a statutory presumption of validity under 35 U.S.C. § 282." *Id.* The Patents-in-Suit "enjoy[] the same presumption of validity during preliminary injunction proceedings as at other stages of litigation." *Id.* at 1377. Therefore, defendants have the burden to come forward with evidence of invalidity. *Id.* If a defendant does so, the Court must decide whether the evidence "raises a substantial question concerning the validity of the patent."

*Id.* at 1378 (internal quotation marks omitted). Accordingly, at this procedural stage, BDC will focus on infringement.

Patent infringement analysis is a two-step process: first the Court construes the language of the claims, and then the properly construed claims are compared to the accused product. *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1372 (Fed. Cir. 2005). In this motion, both apparatus and method claims are at issue. "Direct infringement of an apparatus claim requires that each and every limitation set forth in a claim appear in an accused product." *LifeNet Health v. LifeCell Corp.*, 837 F.3d 1316, 1325 (Fed. Cir. 2016) (internal quotation mark omitted, citation omitted). "Direct infringement of a method claim requires all steps of the claimed method to be performed by or attributable to a single entity." *Id.* In addition to direct infringement, a defendant can be liable for patent infringement if it actively induces infringement of a patent by another. 35 U.S.C. § 271(b). Induced infringement occurs where an inducer takes "an affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1332 (Fed. Cir. 2016).

For simplicity's sake BDC will focus its briefing on only four claims from two of the Patents-In-Suit (two from each).

**a. Claim Construction**

To the extent that the plain meaning of each of the claim terms is not readily apparent, only limited claim construction is necessary to resolve this motion. The only claim term that arguably is in need of construction is "compliance chamber."[3]

Claim terms are to be given their ordinary and customary meaning as determined from the perspective of one of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). The "person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* However, limitations from the specification should not be read into the claims themselves. *Id.* at 1320. No construction is necessary when "the ordinary meaning of claim language as understood by a person of skill in the art [is] readily apparent even to lay judges." *Id.* at 1314.

The term "compliance chamber" means "a cavity or volume that functions to absorb some of the pressure in the system." In the context of the Patents-in-Suit, the specification explains that the "cavity or volume" may contain air or another gas and may directly contact the fluid or may be separated from the fluid by a membrane. '538 Patent col.8, l.66—col.9, l.4. The specification further explains that the chamber or chambers absorb some of the pressure placed upon the fluid in the test chamber and can also impact the recoil. '538 Patent col.8 ll.59-64. col.9 l.4. Likewise, the compliance chamber

[3] Due to the preliminary nature of this motion, BDC reserves the right to modify its construction of this term or to ask for the Court to construe additional terms later.

minimizes the effect of rapidly changing pressure gradients associated with accelerated testing. '538 Patent col.8, ll.64-66.

**b. Comparison of '935 Patent and Accused Device**

BDC is likely to show at trial that TA Instruments infringes (at least) claims 1 and 9 of the '935 Patent. Claim 9 is a dependent claim of claim 1. As shown in more detail in the claim chart in declaration of BDC's expert, all limitations of these claims are found in the DuraPulse. *See* Girard Decl. ¶ 25.

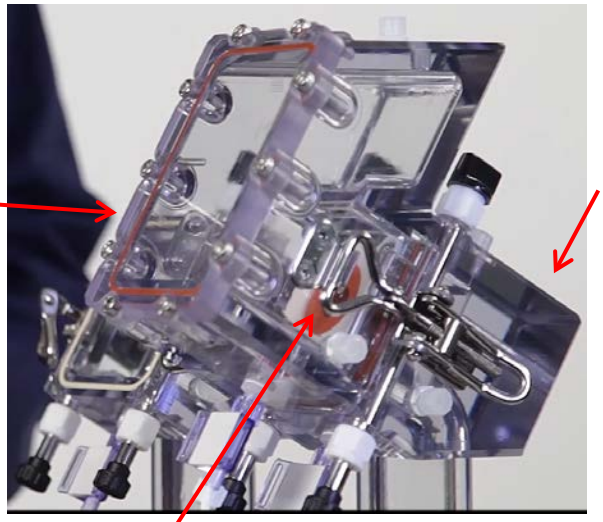
Claim 1 of the '935 Patent (with alphabetic notations for ease of reference) is:

> 1. A device for accelerated cyclic testing of a valved prosthetic device comprising
>
> [A] a pressure source configured to drive a test system fluid cyclically within the device above a normal physiological rate, at an accelerated pulsed rate of greater than 200 beats per minute within the device; and
>
> [B] a pressurizable test chamber for containing the test system fluid and further comprising
>
> [C] a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source;
>
> [D] a fluid return chamber positioned on a second side of the valved prosthetic device;
>
> [E] a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and
>
> [F] an excess volume area capable of operating at the accelerated pulsed rate, wherein the excess volume area is in fluid communication with the fluid return chamber providing a volume for storing a volume of a test system fluid when the test system fluid is under compression.

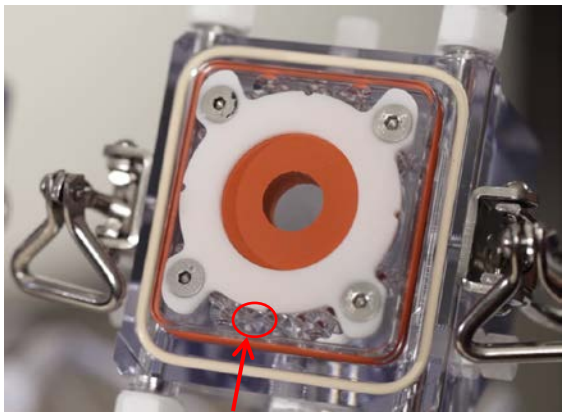
Claim 9 adds the limitation [G] that "the excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber."

These limitations are all present in the DuraPulse. Elements [A] and [B] are shown in this image of the DuraPulse:


Girard Decl. ¶ 24. Elements [C] and [D] are shown in this close-up of the test chamber:



*See* Girard Decl. ¶ 25. Surrounding the sample holder are small holes that work as "fluid return conduits" (element [E]) to connect the two sub-chambers of the test chamber:

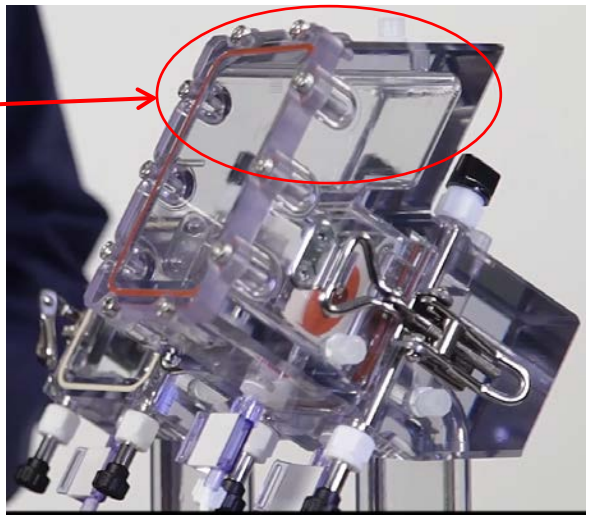


[E]

Girard Decl. ¶ 25 (citing '210 Patent col.9 ll.49-53 & fig.6b).

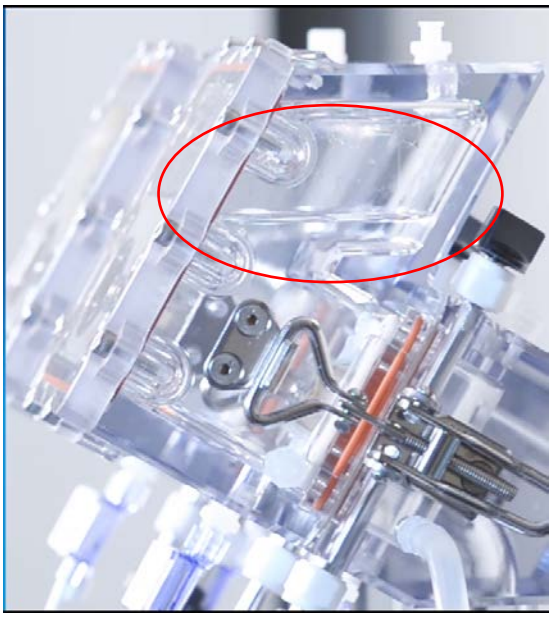
Finally, as shown in this close up of the fluid return chamber, that chamber has an "excess volume area" that constitutes a "compliance chamber" (elements [F] and [G]) at the top:

[F], [G] Excess volume area within fluid return chamber



This area is an excess volume area because when the DuraPulse's test chamber is pressurized, fluid flows through the valve into the fluid return chamber causing liquid

already in that chamber to move into the area circled at the top. *See* Girard Decl. Ex. B at col.11 ll.5-22. The picture below shows the fluid in this area:



Girard Decl. ¶ 25. Moreover, as shown in the picture, the excess volume area is a cavity within the fluid return chamber. *Id.* This excess volume area is also a "compliance chamber" because it can absorb some of the pressure placed upon the fluid. *Id.* When the fluid is compressed and begins to flow into the excess volume area, the air in the excess volume area is likewise compressed. *Id.* This creates a spring force and the air in the excess volume area can function as a type of gas spring to absorb the pressure. *Id.* (citing '210 Patent col.11, ll.8-22,32-34).

Therefore, the DuraPulse has all elements of claims 1 and 9. TA Instruments makes, uses, offers to sell, and sells the DuraPulse in the United States. Weinberg Decl. ¶ 19. Accordingly, BDC is likely to prove at trial that TA Instruments infringes claims 1 and 9 of the '935 Patent.

**d. Comparison of '224 Patent to Accused Device**

BDC is also likely to show at trial that TA Instruments infringes (at least) claims 1 and 6 of the '224 Patent. Claim 6 is a dependent claim of claim 1, and both claims are method claims. As shown in more detail in the claim chart in declaration of BDC's expert, use of the DuraPulse requires performance of all steps recited in those claims. *See* Girard Decl. ¶ 26.

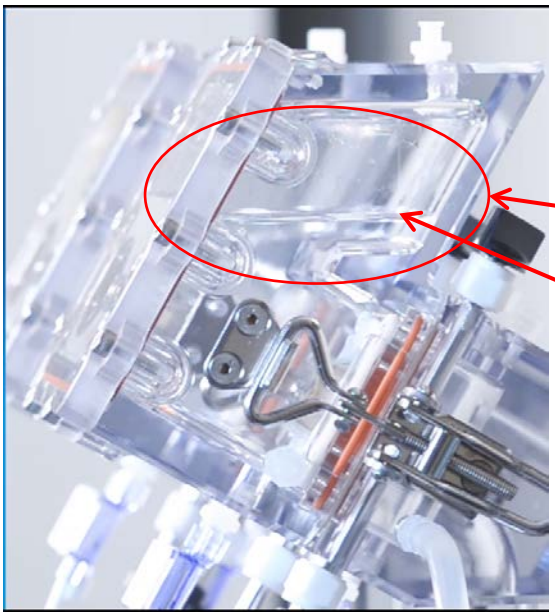
Claim 1 of the '224 Patent (with alphabetic notations for ease of reference) is:

1. A method for operating an accelerated cyclic test system for evaluating a valved prosthetic device comprising

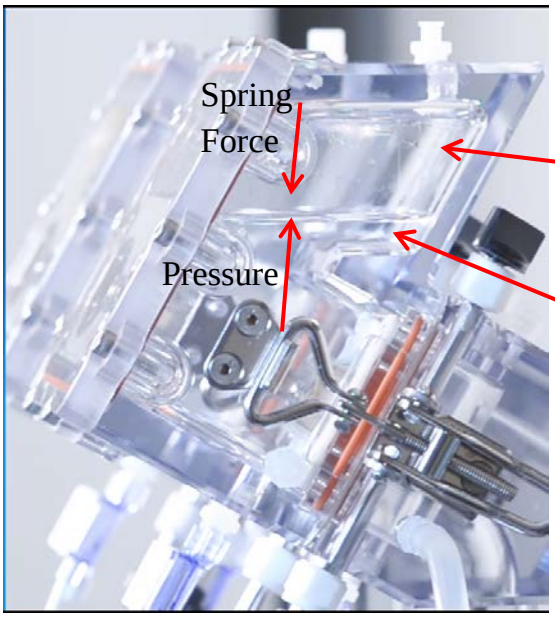
> [A] driving a test system fluid cyclically above a normal physiological rate, at an accelerated pulsed rate of greater than 200 beats per minute within the test system;
>
> [B] storing a volume of test system fluid in an excess volume area during a system driving stroke that opens the valved prosthetic device; and
>
> [C] releasing the stored volume of test system fluid during a return stroke that closes the valved prosthetic device.

Claim 6 adds the additional step of [D] "compressing a volume of a compressible gas with the volume of test system fluid to provide a spring force counter to and in response to a pressure on the test system fluid when the volume of test system fluid is stored in the excess volume area."

As discussed above, the DuraPulse operates [A] at a speed of 900-1800 beats per minute. Girard Decl. ¶ 26. The excess volume area also stores test fluid during the driving stroke of the system [B]:




As explained in BDC's expert declaration and above, during the return stroke, the valve closes and fluid moves through the small holes around the sample holder, draining the excess volume area and meeting element [C]. *Id.* Finally, element [D] is met because the excess volume area can be filled with air that compresses and acts as a gas spring, i.e., providing a spring force in response to pressure from the test fluid:



TA Instruments infringes claims 1 and 6 of the '224 Patent because it uses the DuraPulse for heart valve durability testing and instructs others to do so. It makes claims regarding the efficacy of the DuraPulse system for testing in both its promotion materials and the '210 Patent. In order to make these claims, it must have itself used the DuraPulse system. Weinberg Decl. ¶¶ 19, 24. Therefore, it has directly infringed claims 1 and 6. In addition, TA Instruments was specifically advised that use of its system would infringe the '224 Patent in February 2014. Yet, TA Instruments has continued to advertise to customers that the DuraPulse can be used for heart valve durability testing, and instruct them on how to use the DuraPulse for that purpose (which is its only advertised purpose). *E.g.*, ECF No. 31. Therefore, TA Instruments is also inducing infringement of claims 1 and 6. BDC is likely to prevail on the merits at trial of showing infringement by TA Instruments of claims 1 and 6 of the '224 Patent.

**C. BDC Will Suffer Irreparable Harm Without An Injunction**

BDC practices its patent invention by using and selling the VDT-3600i and, as result, TA Instruments' infringement is causing BDC irreparable harm. The Federal Circuit has recognized several forms of irreparable harm that warrant injunctive relief including lost market share, lost research and development opportunities, injury to reputation and goodwill, and price erosion. *Mylan Inst. LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 872 (Fed. Cir. 2017); *Aria Diagnostics v. Sequenom, Inc.*, 726 F.3d 1296, 1304 (Fed. Cir. 2013); *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1153-55 (Fed. Cir. 2011); *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1566

(Fed. Cir. 1996). Without a preliminary injunction, TA Instruments' sales of the DuraPulse will cause each of these forms of irreparable harm.

**1. Lost Market Share**

The Federal Circuit has recognized that lost market share constitutes irreparable harm, particularly where that lost share is difficult to reverse or quantify due to "incumbency effects," (i.e., markets where customers prefer to remain with an incumbent supplier). *Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1336 (Fed. Cir. 2013). BDC currently enjoys a dominant position in the market for heart valve durability testing systems—having about an 80-90% share of the worldwide market. Weinberg Decl. ¶ 11. BDC attained this position because it was able to offer an innovative product that stood out compared to the antiquated testing systems offered by competitors. *See id.* ¶¶ 9-10. Importantly, BDC's VDT-3600i is not only innovative but it is also dramatically improved the state of the art with respect to accelerated testing of heart valves, an attribute created by its patent protection. *See id.* However, TA Instruments has now entered the market with an infringing product capitalizing on the goodwill, technology and efforts that created BDC's dominant market position. BDC has already begun losing sales to TA Instruments, *id.* ¶ 22, and it is only a matter of time before TA Instruments captures a significant piece of the market. For example, BDC has become aware that TA Instruments is placing its products for testing with other potential customers and has offered customers steep price discounts to "buy" market share. *Id.*

To make matters worse, the market for medical device system has incumbency effects: if BDC loses market share now the lost customers will be lost for the foreseeable

future. In the medical device test systems market, a customer's first purchase is for the purpose of running a pilot testing program. *Id.* ¶ 11. If the pilot test is successful, the customer will then purchase more of the *same* test systems from the same manufacturer as part of a larger testing program for commercial use. *Id.* Once these purchases have been made, it could be up to fifteen years before the customer is in the market to purchase a test system again. *Id.* ¶ 12. Therefore, if TA Instruments is not enjoined now, customers running pilot programs may permanently switch to TA Instruments and BDC will irreparably lose its position in the market place for the foreseeable future.

Moreover, to make matters even worse still, the market for heart valve durability testing systems is small. The market is akin to musky fishing—bites are few but rewards are large. BDC's systems' pricing starts at roughly $71,000, but BDC sells [redacted] systems a year. Weinberg Decl. ¶¶ 22-23. These [redacted] systems annually resulted in 80-90% share of the worldwide market. *Id.* ¶ 11. Accordingly, the market is sensitive to disruption. Even a handful of sales of TA Instruments' infringing DuraPulse system will harm BDC's relationships with customers, harm its reputation as an innovator with a unique product, reduce its research and development activities, and permanently erode its prices (these harms are discussed further below). In such a market, BDC cannot simply be put back into position at the end of trial. *See Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975-76 (Fed. Cir. 1996) ("years after infringement has begun, it may be impossible to restore a patentee's [] exclusive position by an award of damages and permanent injunction."). Indeed, the entire value of BDC's patents is to protect its exclusive position in the market. *See, e.g.*,

*Edwards Lifesciences AG v. CoreValve, Inc.*, 699 F.3d 1305, 1314 ("A patentee's right to exclude is a fundamental tenet of patent law."). Without that exclusivity, BDC will be irreparably harmed.

**2. Lost Research and Development Opportunities**

Lost market share for BDC also constitutes irreparable harm because of the intangible effect it will have on BDC's research and development efforts. *See Mylan*, 857 F.3d at 872 (upholding district court's finding that patent owner would suffer irreparable harm if forced to reduce its research and development activities as a result of infringement); *Bio-Technology General*, 80 F.3d at 1566 (same). The market for testing systems is one in which a company's innovation must match the innovation of its customers (who make medical devices). *See* Weinberg Decl. ¶ 4. To keep up with the advancements in medical devices, BDC uses part of its revenue from its sales to fund its research and development for new devices. *Id.* ¶ 13. Indeed, to develop the technology behind the Patents-in-Suit, BDC dedicated a team of three inventors, out of five total employees, who spent years perfecting the test system. *Id.* ¶ 3. To say that research and development is important in this industry is an understatement.

Lost sales for BDC of VDT-3600i will negatively impact all of its business because it will have less revenue to fund research and development. This is particularly true because the VDI-3600i is part of BDC's core business; it is its bestselling test system. *See EcoNova Inc. v. DPS Utah*, No. 1:12-CV-174, 2012 WL 5944257, at *14 (D. Utah Nov. 28, 2012) ("The fact that the patented product is at the core of the patent holder's business can support a finding of irreparable harm."). Without the revenue to

fund research and development across all its business, BDC will suffer the intangible injury of losing pace with the innovation of its customers and competitors. Innovation is a time-consuming step-by-step process, and BDC cannot be simply leap back into pace with the award of a royalty at the end of trial.

**3. Harm to Reputation for Innovation**

As explained by the Federal Circuit, it is irreparable harm for a patentee to "lose some of its distinctiveness and market lure" if "competitors could contend they had 'similar feature' without noting that those feature infringes [the patentee's] proprietary technology." *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344 (Fed. Cir. 2013). The DuraPulse system is threatening the "market lure" of BDC's VDT-3600i system and harming BDC's reputation for innovation.

BDC has a reputation for innovation and associated customer goodwill. For example, customers have stated that:

- "Questions that other companies will not be able to answer will be answered by [BDC]"
- "[BDC's] testing is more likely to meet dynamic regulatory requirements"
- "BDC is a true partner with our R&D team"
- "The novel design and implant location of [a customer's] device meant that standard reliability testing equipment was not applicable. Custom equipment designed from scratch would be required. Working with BDC, we were able to quickly build a test fixture . . . ."
- "[BDC is] an excellent thought partner in problem solving."

http://www.bdclabs.com/about-us/client-testimonials/. Contributing to BDC's reputation for innovation is the fact that the VDT-3600i was a differentiated product for heart valve testing—it was the only type of machine on the market. In fact, the VDT-3600i became the "industry standard" for prosthetic heart valve durability testing. Weinberg Decl. ¶ 10.

However, BDC's VDT-3600i is no longer a differentiated product given the presence of TA Instruments' infringing DuraPulse system in the market. Once lost, BDC's reputation cannot be regained and cannot be compensated through money damages. The threat to BDC of losing its position as having the industry standard technology is irreparable harm to its reputation for innovation. *Wald v. Mudhopper Oilfield Serv.*, No. CIV-04-1693, 2006 U.S. Dist. LEXIS 51669, at *16 (W.D. Okla. July 27, 2006). Accordingly, injunctive relief is appropriated.

**4. Price Erosion**

TA Instruments' infringement is also threatening BDC with price erosion. Price erosion constitutes irreparable harm. Courts have routinely recognized in patent disputes that once prices have been lowered by infringing activity, patent owners cannot raise prices back to pre-infringement levels without damaging customer goodwill because customers have become accustomed to prices artificially deflated by infringing activity. *See Celsis In Vitro*, 664 F.3d at 930; *Bridwell*, 103 F.3d at 975 ("Requiring purchasers to pay higher prices after years of paying lower prices to infringers is not a reliable business option."); *Cornucopia Prods., LLC v. Dyson*, Inc., Nos. CV 12-00234, 12-00924, 2012 U.S. Dist. LEXIS 104750, at *28 (D. Ariz. July 27, 2012) ("[P]rice erosion, in particular,

may be irreversible regardless of an ultimately favorable outcome for [the patent owner].").

Here, BDC's list price for the VDT-3600i starts at about $71,000. TA Instruments list price for a comparable system is about $100,000. However, TA Instruments has begun offering discounts on its systems in order to undercut BDC's price. BDC has lost at least one customer to TA Instruments based on TA Instruments' lower price offer. Weinberg Decl. ¶ 22. Given that TA Instruments' starting list price is about $30,000 higher than that of BDC, the price breaks must be very large. As a result, BDC has begun to experience price pressure from other customers. *Id.* Therefore, unless TA Instruments' infringement is enjoined, BDC will likely have to lower its prices. Once lowered, its prices will have been permanently eroded, causing BDC irreparable harm. Therefore, TA Instruments' infringement should be enjoined.

**5. BDC Did Not Delay In Brining Motion**

In response to this motion, TA Instruments may argue that BDC's motion should be denied because of the delay between the time BDC learned of TA Instruments infringement in December 2015 and the time BDC filed its motion. Delay is a factor to be considered in assessing irreparable harm, but "it is not dispositive of determining there was no irreparable harm." *Encap LLC v. Oldcastle Retail Inc.*, Case No. 11-C-0808, 2012 U.S. Dist. LEXIS 69587, at *38-39 (W.D. Wis. May 18, 2012). In assessing the impact of delay, courts should examine the cause of the delay. For example in *Encap*, the Court excused an almost four year delay because the patentee was waiting for a stronger patent to issue, the parties had been engaged in settlement discussions, and price erosion

had only recently become a serious threat. *Id.* at *39-40. Similarly in *Brushnell Inc. v. Brunton Co.*, the Court excused a twenty-three month delay where the infringing product had only recently become a "real threat" and the patentee wanted to take a "prudent and cautious approach" before initiating a round of "expensive and distracting" patent litigation. 673 F. Supp. 2d 1241, 1263-64 (D. Kan. 2009). *See also Marks Org., Inc. v. Joles*, 784 F. Supp. 2d 322, 333 (S.D.N.Y. 2011) (noting that "[d]ecisions also acknowledge that diligent pursuit of settlement negotiations can justify delay").

Any delay in filing this motion for preliminary injunction is excusable. BDC is a small company—it currently has only about five or six employees working on its testing equipment business. Weinberg Decl. ¶ 3. Rather than immediately jump into expensive and distracting litigation (particularly with a large company such as BOSE, which originally sold the DuraPulse), BDC decided to take a prudent and cautious approach and diligently pursue resolution when necessary. BDC first attempted to notify BOSE of its potential infringement. *Id.* ¶ 16. BOSE denied infringement of the only two patents that had issued at the time and refused to discuss a patent application that was pending. *Id.* ¶ 17. BOSE then sold the product line that included the DuraPulse system to TA Instruments. *Id.* ¶ 18. TA Instruments' increased advertising of the DuraPulse and finally provided information with which BDC could confirm infringement. *Id.* ¶¶ 18-19. Thereafter, BDC engaged in a series of discussions with TA Instruments concerning its product and the patents to reach a settlement that would avoid irreparable harm to BDC. *Id.* ¶ 20. However, after more than a year of exchanging correspondence, the settlement negotiations reached an impasse. *Id.* ¶¶ 20-22.

Significantly, during the discussions, the DuraPulse system went from a little known product to a legitimate threat to BDC's market position. After BOSE sold the rights to the system to TA Instruments, TA Instruments dramatically increased its marketing efforts. *Id.* ¶ 18. As a result, the threat of harm caused by TA Instruments is now much more significant. Specifically, several months ago, BDC lost a sale in head-to-head competition with TA Instruments, in part due to TA Instruments' undercutting BDC's price. *Id.* ¶ 22. *Encap* and *Brushnell* are directly on point. Accordingly, the Court should follow these cases and reject any arguments by TA Instruments that any perceived delay should weigh against issuance of a preliminary injunction

**D. Balance of the Harms**

The balance of harms favors an injunction. As discussed above, the harm to BDC of TA Instruments' infringement is substantial and irreparable. On the other hand, the only harm to TA instruments is cessation of infringing sales that it had no right to make in the first place. *See Apple, Inc. v. Samsung Elecs. Co.*, No. 11-CV-01846, 2012 WL 2401680, at *2 (N.D. Cal. June 26, 2013) ("[O]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against a continuing infringement destroys the business so elected.") (quotation omitted).

**E. Public Interest**

The public interest also favors issuance of a preliminary injunction to protect BDC's patent rights. "Protecting patents from would-be infringers is always acting in the public interest." *Schneider (Europe) AG v. SciMed Life Sys., Inc.*, 852 F. Supp. 813, 861 (D. Minn. 1994).

**F. Bond**

Bond in this case should be minimal. District courts have broad discretion in determining the amount of a bond to secure a preliminary injunction. *Hill v. Xyquad, Inc.*, 939 F.2d 627, 632 (8th Cir. 1991). BDC's infringement case is strong. Moreover, TA Instruments' in only just beginning to make inroads into the domestic market for heart valve durability testing systems; TA Instruments' counsel has indicated that total revenue of the product to date is just over $100,000 as it is still in somewhat of a start-up phase of its product. Therefore, the potential lost profits to TA Instruments of a preliminary injunction at this early stage of TA Instruments' sales and marketing are still likely small. In light of these circumstances, bond should be $10,000.

## CONCLUSION

For the reasons stated herein, BDC respectfully requests that this Court put a stop to TA Instruments' infringement, and enter a preliminary injunction consistent with BDC's proposed order.

Dated: November 22, 2017

DORSEY & WHITNEY LLP

By /s/Forrest Tahdooahnippah

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# Exhibit B

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

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Biomedical Device Consultants & Laboratories of Colorado, LLC,

Plaintiff,

v.

TA Instruments – Waters, LLC,

Defendant

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Civil File No. 0:17-cv-03403

**DECLARATION OF CRAIG WEINBERG IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION**

I, Craig Weinberg, hereby declare and state as follows:

1. I am the President and CEO of Plaintiff Biomedical Device Consultants & Laboratories of Colorado, LLC ("BDC"). I make this Declaration in connection with BDC's motion for a preliminary injunction. I have personal knowledge of the matters set forth below and, if called as a witness, I could and would testify as follows.

**Background**

2. I received my Ph.D. in the area of Mechanical Engineering with a focus in cardiovascular fluid dynamics from the University of Colorado in 2003. In early 2011, I began to serve on the US sub-committee and then, as of January of 2015, began serving on the parent international committee ISO/TC 150/SC 2/WG 1, which is the group that creates the international guidance documents for design verification/validation evaluation of heart valves and heart valve repair devices. As a result, I am very familiar with all the commercially available products that are part the functional performance evaluation, both real-time and accelerated, utilized during the verification/validation testing of the

associated devices.

3. In 2006, I joined BDC as its president. In about February 2008, a team of three people—myself, Benjamin McCloskey, and Dr. Steven Weinberg—began researching and designing a new prosthetic heart valve and venous valve durability testing system. The dedication of a three person research team to this project was a significant investment for BDC. Though BDC currently has five or six employees solely devoted to working on its testing equipment business, back at the time of the invention in 2008, the entire company was only on the order of five full time employees.

4. The nature of BDC's business requires that it make these types of significant investments in research and development. BDC's customers are those that wish to test medical devices, often the medical device manufacturers themselves testing the device to obtain regulatory approval. The medical device industry is an innovative industry—new and improved medical devices enter the market all the time. These new devices often require state of the art testing systems for their evaluation. For example, prosthetic heart valves have seen significant improvements in recent years resulting in larger sizes and different methods of for securing in place within the human body (e.g. transcatheter heart valves). This has required similar innovations in the equipment available to test the valves. Therefore, to stay competitive, BDC must keep pace with the innovation of both its customers and its competitors.

5. Our research, with respect to heart valve durability test equipment, eventually led to the issuance of four patents, U.S. Patent Nos. 8,584,538 ("the '538 Patent"), 8,627,708 ("the '708 Patent"), 9,186,224 ("the '224 Patent"), 9,237,935 ("the

'935 Patent") (collectively, "the Patents-in-Suit"). I am a named inventor for all four patents.

**BDC's Innovative VDT-3600i System is Market Leading Test System**

6. Before the Patents-in-Suit, heart valve durability testing systems on the commercial market used drive motors that resulted in minimal control of the differential pressure rate and spikes associated with valve closure that could result in unnecessary early deterioration of the test valves and potential false test failures. To better manage valve closing dynamics and differential pressure spikes, and thus better comply with the durability testing standards, myself and the co-inventors of the Patents-in-Suit developed a novel test system that placed an excess volume area on the outflow side of a test sample valve. We also developed a method of operating the test system to help control and minimize differential pressure loading and associated spikes.

7. The reduction in differential pressure spikes during closure in the accelerated flow system was further aided by the use of a "compliance chamber." A compliance chamber is an area usually filled with air or gas within a test system that permits a change in its volume with an associated change in system pressure. In our design, we positioned a compliance chamber downstream of the test sample. It acts similar to a spring and stores pressure in the system during the "drive" phase (the phase the opens the test valve) and then releases it during the "return" phase (the phase that closes the valve).

8. The Patents-in-Suit revolutionized the market for heart valve durability testing systems by providing an accelerated testing device with a compliance chamber on

the outflow side of the valve and a non-symmetrical waveform driving signal. BDC has commercialized the Patents-in-Suit through a product known as the VDT-3600i heart valve durability tester.

9. The VDT-3600i has been a tremendous success. When it was released it was a unique and differentiated product. It was the only testing system on the market that used a non-regular signal input to the drive motor and provided an excess volume area in a return chamber, downstream of the valve to store fluid during the driving phase of the system. This excess volume area and use of a non-regular driving waveform are significant improvements in accelerated test system design. The signal form better controlled the test valve loading and reduced the differential pressure spike while better meeting the test standard for holding a pressure differential across the valve without excessive pressure loading. The excess volume area further provided for storage of pressure which improved our system's ability to test heart valves at an accelerated rate in an efficient and controlled manner.

10. The market for heart valve durability testing systems is highly specialized and therefore is also very small. There are only four competitors in the market. These competitors currently are my company BDC, Defendant TA Instruments-Waters LLC ("TA Instruments"), Dynatek Labs, and ViVitro Labs. When the VDT-3600i was released, the only competitors were Dynatek and ViVitro. Dynatek's system, however, used old, outdated technology. As a result, it was, and is, not considered a viable alternative in the marketplace for the latest valve technology and currently has few sales, if any. Similarly, ViVitro's testing system relies on movement of an artificial heart valve

through fluid to create the valve opening and closing, not movement of fluid through a valve, which is thus not testing the valve in clinically representative manner. Once the VDT-3600i entered the market, ViVitro's technology was deemed not commercially relevant or equivalent to the VDT-3600i. Therefore, as a superior and unique product, the VDT-3600i rapidly (within five years) became the industry standard for heart valve durability testing systems.

11. BDC's VDT-3600i currently has about an 80-90% share of the worldwide market for heart valve durability testing systems. Market share in the heart valve durability testing equipment market is extremely important due to the incumbency effects. A single testing system can only test a few devices at a time. (For example, both BDC and TA Instruments sell systems that test a maximum of six prosthetic heart valves at a time). To bring a new prosthetic valve device to market, however, medical device manufacturers need testing data from many, often dozens, of sample devices. Therefore, testing system customers need multiple systems. Customers will generally purchase a single testing system and run a short pilot program. If the pilot test is successful, the customer will then purchase more of the same test systems from the same manufacturer as part of a larger testing program for commercial use.

12. Customers generally do not buy testing equipment for a single device from multiple sources in order to avoid introducing additional testing variables (i.e., differences between testing machines from different suppliers) into the test data that would be submitted to the FDA, or international regulatory agencies. The lifespan of valve durability testing equipment is often ten to fifteen years, meaning that once a

customer has decided which testing equipment to use, it will likely be a long time before a competitor has the opportunity to usurp the place of an incumbent.

13. A company's ability to maintain market share is crucial to its long-term success. As I previously mentioned, research and development is vital to a company in this industry so that it can keep pace with its customers and competitors. In order to fund this research and development, BDC uses part of its revenue from its sales to fund its research and development for new devices. The VDT-3600i is of particular significance to BDC because it is BDC's best-selling test system. Therefore, lost sales of the VDT-3600i will negatively impact all of BDC's business because it will have less revenue to fund its research and development across its platform.

14. In this industry, market share is also often linked to reputation for innovation. As I mentioned before, innovation is extremely important. Accordingly, customers often make decisions based on reputation for innovation, and a testing system supplier's long-term success is dependent on that reputation. BDC has a reputation for innovation and associated customer goodwill. For example, the BDC website has numerous customer testimonials discussing BDC's work to innovatively solve problems posed by customers. http://www.bdclabs.com/about-us/client-testimonials/. Contributing to BDC's reputation for innovation is the fact that the VDT-3600i is a differentiated, patented product for heart valve durability testing.

**DuraPulse System Threatens VDT-3600i Market Position**

15. However, the VDT-3600i is no longer a completely unique product because TA Instruments sells a similar system that infringes the Patents-in-Suit known as the

DuraPulse Heart Valve Test Instrument (the "DuraPulse").

16. I first became aware of the DuraPulse in about October 2013, when I observed a prototype of the DuraPulse system at a tradeshow. The DuraPulse is part of a product line known as ElectroForce, which at that time was being developed by Bose Corporation ("BOSE"). Based on my observations of the DuraPulse in late 2013, I was concerned that it may infringe those of the Patents-in-Suit issued at that time. In July 2014, I learned that BOSE was offering the DuraPulse for sale. I sent a letter to BOSE notifying it that the DuraPulse may infringe the '538 Patent and the '708 Patent, and would infringe the '935 Patent once issued (the patent application was still pending at the time). The application for the '224 Patent had not yet been filed. At that time, I did not have detailed information about the operation of the BOSE DuraPulse and thus could not definitively determine many aspects of its operation.

17. BOSE responded to my letter saying that it did not infringe the '538 and '708 Patents and refused to address the application for the '935 Patent, as it had not yet issued. At the time, I did not want to file an infringement lawsuit or seek an injunction for several reasons. I had only limited information about the operation of the DuraPulse system and did not have access to a product. BDC also still had a patent application pending that I thought might warrant inclusion in a potential lawsuit. Finally, at the time, BOSE's potential infringement was not an imminent threat to the market position of VDT-3600i. BOSE's sales and marketing of the DuraPulse appeared to be negligible and I was not aware of any lost sales. As patent litigation is very expensive and BOSE is a much larger company than BDC (both now and at the time), filing a lawsuit based on

limited information and with uncertainty about any actual damage made little sense at the time.

18. In late May 2015, BOSE sold the ElectroForce division and product line, which included the DuraPulse, to TA Instruments. After acquiring ElectroForce, TA Instruments dramatically increased its marketing efforts for the DuraPulse.

19. I studied the promotional materials for DuraPulse that TA Instruments had made available. It became clear to me that the DuraPulse infringed the Patents-in-Suit, especially the patents that had recently been issued (the '224 Patent, which issued on November 17, 2015, and the '935 Patent, which issued on January 19, 2016). Based on information from its marketing materials, TA Instruments makes, sells, and offers to sell the DuraPulse in the United States. TA Instruments also uses the DuraPulse for heart valve durability testing. It makes claims regarding the efficacy of the DuraPulse system for testing in its promotion materials. In order to make these claims, it must have itself used the DuraPulse system. TA Instruments also advertises to customers that the DuraPulse can be used for heart valve durability testing, and instructs customers how to use the DuraPulse for that purpose (which is its only advertised purpose).

20. On February 23, 2016, I sent a letter to TA Instruments notifying it of its infringement of the Patents-in-Suit. Because BDC is a small company and patent litigation is expensive both in terms of money and in terms of employee time, I thought it would be prudent to negotiate a resolution with TA Instruments as long as the terms of any potential agreement that could protect BDC's market position in terms of reputation, price, and innovation. To that end, BDC and TA Instruments engaged in a series of

communications concerning TA Instruments' defenses to BDC's claims for over a year.

21. While these settlement discussions were ongoing, TA Instruments' increased marketing efforts for the DuraPulse began to pay off and its infringement became a real threat to BDC.

22. In February 2017, while the parties were exchanging settlement correspondence, BDC lost a sale of the VDT-3600i to TA Instruments' DuraPulse system in head-to-head competitive bidding for a customer. The customer told me that price was a consideration in why the customer purchased from TA Instruments and not BDC. This was surprising because BDC's list price for the VDT-3600i starts at roughly $71,000 and the DuraPulse starts at $100,000. In order to undercut BDC's price, TA Instruments is apparently offering discounts to customers to attract business and "buy" market share. BDC is now experiencing price pressure, potential customers for the VDT-3600i are asking for price concessions. As a result of the timing of this sale and the content of TA Instruments' settlement communications, it became clear to me that TA Instruments was simply trying to draw out the discussion while improving its position in the market.

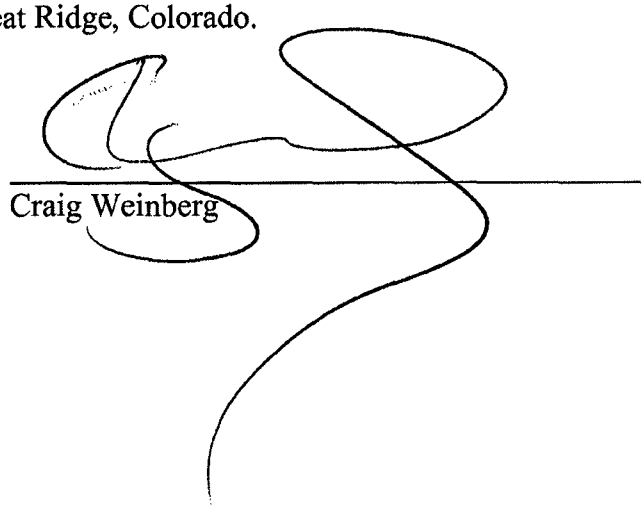
23. Even one lost sale to TA Instruments is a significant threat to BDC because the market is very small. Systems are expensive, and BDC only sells between [redacted] systems a year. The market is therefore sensitive to change. With TA Instruments winning bids against BDC, BDC is in immediate threat of losing its market lure as a unique, patented product. This will lead to BDC losing more market share and losing its reputation for innovation. BDC will also have less revenue to dedicate to research as a result of less sales and potentially being forced to lower its prices to stay

competitive.

24. In addition, I became aware of U.S. Patent No. 9,662,210 ("the '210 Patent"), which was originally applied for by Bose in January 2014 and acquired by TA in May 2015. The '210 Patent describes the operation of an accelerated valve test system that looks like the DuraPulse from the figures. I recently (September 2016) had the opportunity to observe the DuraPulse system in operation, and my observations confirmed that the '210 Patent describes the operation of the DuraPulse. The description of the DuraPulse in the '210 Patent confirms that the system infringes the Patents-in-Suit and also confirms that the system has been used by TA Instruments itself (not just its customers). TA Instruments has continued to make use, offer for sale, and sell the DuraPulse even after being specifically advised in February 2016 that such activities would infringe the claims of the Patents-in-Suit.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on November 22, 2017 in Wheat Ridge, Colorado.



Craig Weinberg